

REMARKS

Claims 1-58 and 60-75 were pending in the subject application. Claims 47, 49, 51, 53-56, 58, 61, 68, and 71 have been amended hereinabove and claim 75 has been cancelled. Claims 9, 28-41, and 64-66 have been withdrawn from consideration by the Patent Office. Accordingly, claims 1-58 and 60-74 are pending and claims 1-8, 10-27, 42-58, 60-63, and 67-74 are under consideration at this time. Reconsideration is requested in view of the above amendments and following remarks.

Claims 47, 49, 51, 53-56, 58, 61, 68, and 71 appear to have been deemed allowable but for their dependence upon a rejected claim. Applicants have rewritten these claims in independent form. Accordingly, allowance of these claims is earnestly solicited.

The Patent Office has maintained its rejection of claims 1-8, 10-27, 42, 45, 46, 48, 50, 52, 57, 60, 62, 63, 67, 69, 70, and 72-75 under 35 U.S.C. § 112, second paragraph, because the phrase "pharmaceutically acceptable esters" is alleged to be indefinite.

Contrary to the position of the Patent Office, applicants' claims fully satisfy the requirements of 35 U.S.C. § 112, second paragraph. The phrase "pharmaceutically acceptable esters" is definite and recited in numerous issued U.S. patents. Whether or not the Patent Office agrees "the specification teaches preparing esters of the instant compounds in the specification" is irrelevant to a rejection under 35 U.S.C. § 112, second paragraph. Such an argument would go to enablement or written description under 35 U.S.C. § 112, first paragraph. While the phrase "pharmaceutically acceptable

esters" may be broad, it is clearly definite as evidenced by the Patent Office's issuance of numerous patents having claims containing such phrase.

With respect to enablement (i.e. had a rejection been made under 35 U.S.C. § 112, first paragraph), applicants point out that the formation of pharmaceutically acceptable salts and esters of compounds is well known in the art and fully supported by applicants' specification. Applicants note that the specification at page 8, paragraph [0026], describes "pharmaceutically acceptable esters" as "esters of the compounds of formula (I), in which hydroxy groups have been converted to the corresponding esters....." Independent claims 1 and 24 properly embrace "pharmaceutically acceptable esters" of formula (I) and formula (Ia), respectively, because the substituents A² and R² of claim 1, and substituent A¹² of claim 24, may have hydroxy.

It is applicants' position that the phrase "pharmaceutically acceptable esters" is both definite in accordance with 35 U.S.C. § 112, second paragraph, and enabled under 35 U.S.C. § 112, first paragraph.

The Patent Office also maintained its objection of claims 1-7, 10-27, 42, 60, 62, 63, and 73-75 due to an allegedly improper Markush group. This objection stems from the Patent Office's determination that W and X are critical to the common core of the instant compounds. While applicants appreciate the Patent Office's suggestion to amend the claims to read upon the elected group to overcome this objection, applicants are not making such an amendment at this time.

Applicants agree that W and X are critical to the common core of the claimed compounds. However, it is applicants' definition of W and X that should be controlling, not the Patent Office's definition. The Patent Office has no right to create a generic concept and require applicants to limit their invention to such concept. Accordingly, no objection under the doctrine of improper Markush group should be sustained.

It is well-established law that restriction within a single claim cannot be sustained under 35 U.S.C. §121. As is stated in *In re Weber*, 198 U.S.P.Q. 328 (CCPA 1978) at pages 331-332,

"§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It is not, however, provide a basis for the Examiner acting under the authority of the Commissioner to *reject a particular claim* on that same basis." (Emphasis in original text).

The court went on to further state that:

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

Applicants have the right under U.S. patent law to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the

Serial No. 09/939,872
Filed: August 27, 2001

requirements of 35 U.S.C. §112 are met. See *In re Weber* at 331. In addition, MPEP 809.02(c) states "An examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species."

Assuming *arguendo* that the restriction requirement was correct (applicants reserve their right to petition this issue), the Patent Office would still be obligated to examine on the merits the entirety of applicants claims that have not been withdrawn from consideration in whole.

In view of the above, applicants request reconsideration, withdrawal of all rejections under 35 U.S.C. §112, second paragraph, and all objections based on improper Markush group.

Claim 75 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabling for diseases claimed. Merely to expedite prosecution, applicants have hereinabove cancelled this claim without prejudice to prosecuting this claim in a future application that claims the benefit of the subject application's filing date. Accordingly, this rejection is now moot.

Claims 1-6, 8-27, 42-44, 59-63, 67-71, and 73-75 were rejected as allegedly being obvious in view of Aebi (U.S. Patent No. 6,034,275). The essence of the rejection appears to be that the Aebi disclosed compounds of Formula Ie that are

structural homologues of applicants' claimed compounds when W or X is SO₂, n is 0, and V is O and that it would have been obvious to modify these compounds to arrive at applicants' claimed compounds.

While the above rejection may apply to generic claims 1 and 24, such a rejection is in appropriate where applicants' compounds are not structural homologues. In claims 4 and 63-72, V is -C≡C-, not O. In claims 5, 60, and 61, V is -CH₂-, not O. In claim 62, V is -CH=CH-, not O. There is no teaching or suggestion in Aebi to make such a substitution in the center of the molecule. In the absence of evidence to the contrary, these claims cannot be considered obvious over Aebi.

The same applies to situations where W or X are not SO₂. In claim 9, W is CO, not SO₂. In claims 28-37, X is CO, not SO₂. In claims 38-41, X is COO, not SO₂. In claims 45-58, X is SO₂NH, not SO₂. There is no teaching or suggestion in Aebi to make such a substitution in the molecule. In the absence of evidence to the contrary, these claims cannot be considered obvious over Aebi.

Aebi provides no guidance with respect to modifying the compounds disclosed to obtain applicants' claimed compounds. Without such guidance, there would be no motivation for a person of ordinary skill in the art to have sought to modify Aebi in order to arrive at applicants' claimed invention.

With respect to generic claims 1 and 24, applicants would consider submitting data that evidence superior monooxidosqualene levels in hamster liver by applicants' claimed compounds.

Serial No. 09/939,872
Filed: August 27, 2001

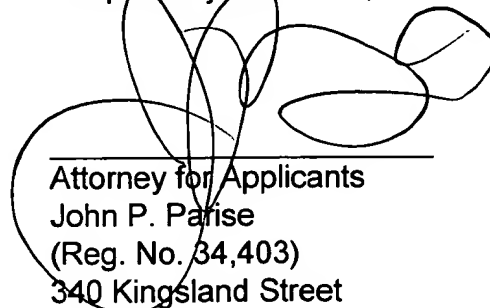
In view of the above, applicants request reconsideration and withdrawal of all rejections under 35 U.S.C. § 103.

In summary, applicants request reconsideration, withdrawal of all rejections and the issuance of a Notice of Allowance.

If a telephone conference would be of assistance in furthering prosecution, applicants request that the undersigned attorney be contacted at the number below.

No fee, other than the fee for a one-month extension of time and the presentation of new independent claims, is required in connection with the filing of this Amendment. If any fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

A large, stylized handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke at the end, positioned over the printed name and address.

Attorney for Applicants
John P. Parise
(Reg. No. 34,403)
340 Kingsland Street
Nutley, New Jersey 07110
Telephone: (973) 235-6326
Telefax: (973) 235-2363

132911